

USARIEM TECHNICAL REPORT T 00/22

**EVALUATION OF A CONTINUOUSLY RECORDING AMBULATORY PULSE
OXIMETER DURING A MOUNTAINEERING EXPEDITION**

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EXECUTIVE SUMMARY

We report a field trial of a novel, continuously recording ambulatory pulse oximeter. Seven military mountaineers climbed Mt. Logan, Canada, in June 1999. During the ascent, they carried an ambulatory pulse oximeter that was designed to perform frequent, round-the-clock measurements of altitude, oxygen saturation and pulse rate. None of the devices performed to expectations, due to a variety of problems with the hardware, software and human factors issues. However, we were able to obtain a recording from one individual that showed both episodic nocturnal desaturations and desaturation during exercise during a single 24-hour period. Additionally, an analysis of distributions of oxygen saturations in one climber revealed an increasing interquartile range and a decreasing median oxygen saturation between base camp (altitude 2760 m) and camp 1 (altitude 3460 m). We conclude that continuously recording ambulatory pulse oximetry is a theoretically interesting but unproven concept in mountain expedition research, and recommend that the devices be redesigned, rebuilt and retested.

INTRODUCTION

Military operations in mountainous terrain are among the most difficult to support medically. The physical environment often places climbers at risk of environmental illness and injury from hypobaric hypoxia, cold, and intense solar radiation. Unfortunately, few medical personnel have the specialized skills needed to accompany a climbing expedition, and even when they can, their ability to provide care is limited by logistical considerations, such as the inability to carry more than a minimal set of medical instruments and supplies. Thus, there is a perceived need for physiologic monitors that are lightweight, highly portable, rugged, and capable of providing real-time, pertinent information to medical personnel. The Warfighter Physiological Status Monitoring (WPSM) program at USARIEM has been developing such technologies.

There is evidence that suggests that climbers with a lower oxygen saturation at altitude are at increased risk for developing altitude illness (2,3,6). For example, a recent study on Denali (6) demonstrated that climbers with lower oxygen saturations at 4200 m were at increased risk for subsequently developing acute mountain sickness (AMS). In another recent study, conducted during a climb of Mt. Sanford, AK, (4949 m) (7), the mean resting oxygen saturation of asymptomatic climbers diminished linearly with increasing altitude up to ~3400 meters (the highest altitude at which measurements were taken). During this expedition, one climber developed AMS that was preceded by a transient, relative desaturation (defined as 2 or more standard deviations below the mean). A second climber developed high altitude pulmonary edema (HAPE) that was accompanied by severe desaturation. These reports suggest that, with further refinement (such as the ability to record oxygen saturations continuously), pulse oximetry might help identify individuals at increased risk for altitude illness and might also be used to monitor those who do become symptomatic.

We report a test of a novel pulse oximeter that was designed to record oxygen saturations continuously during a climbing expedition to Mt. Logan, the second-highest peak in North America.

MATERIALS AND METHODS

RESEARCH VOLUNTEERS

Six Canadian members of the Princess Patricia's Canadian Light Infantry Regiment and one U.S. member of USARIEM gave consent to participate in the testing in accordance with U.S. Army Regulation 70-25 (4). Prior to deployment, the climbers underwent measurement of FEV₁ and FVC with a hand-held spirometer (Micro Spirometer, Micro Medical Ltd., Kent, UK), and measurement of baseline oxygen saturation with a hand-held pulse oximeter (Model 8500, Nonin Medical Inc., Plymouth, MN) equipped with a clip-on fingertip sensor. Ten days prior to the expedition, the climbers spent four days training in the Columbia Icefields (Alberta, Canada) at altitudes of around 3000 m.

The baseline characteristics of the climbers are listed in Table 1. Two

Table 1. Baseline Characteristics of the Climbers.

Climber Number ¹	Age	Pack-Years of Smoking	Current Smoker?	Body Mass Index (kg/m ²)	Baseline SpO ₂ (%) ²	FEV ₁ /FVC Ratio	Significant Medical History
1	39	0	No	29.9	98	0.822	Asthma
2	36	0	No	22.5	98	0.759	
3	32	4	No	27.8	94	0.790	
5	38	12	Yes	21.7	96	0.784	
6	28	0.4	No	25.2	98	0.652	Recent cold
7	38	0	No	31.9	97	0.766	Possible asthma
8	33	10	No	26.3	96	0.768	

¹The number corresponds to the serial number of the pulse oximeter tested; there was no serial #4 on this expedition.

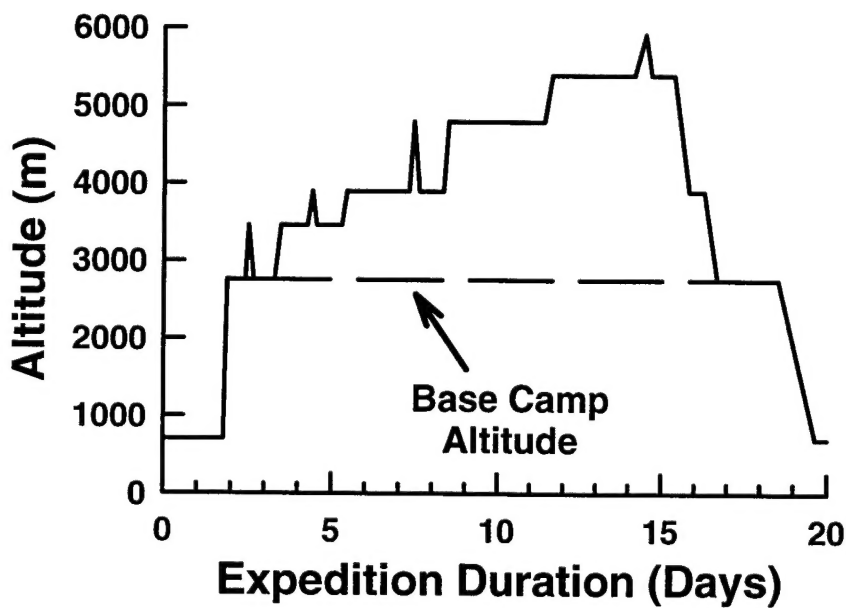
²Taken at Edmonton, AB, Canada (alt. 655 m), after the training expedition to the Columbia Icefields, but before deployment to Whitehorse.

climbers had clinical histories suggestive of asthma with exercise-induced bronchospasm; both were given salmeterol inhalers to use during the expedition. One climber was a heavy current smoker and three climbers were previous smokers. One climber (climber #6) had suffered a recent upper respiratory infection and had mild wheezing on forced expiration. Although his FEV₁/FVC ratio suggested the presence of an obstructive ventilatory defect, this was due to an exceptionally large FVC (130% of predicted) rather than an abnormally low FEV₁ (103% of predicted). None of the climbers had abnormal oxygen saturations at baseline.

EXPEDITION ASCENT PROFILE

The ascent profile for the expedition is shown in Figure 1. The expedition was staged from Whitehorse, Yukon, Canada (elevation 705 m). The climbers were flown to a Base Camp on the King's Trench Glacier of Mt. Logan (elevation 2760 m). From there, a series of four camps were established en route to the

Figure 1. Mt. Logan expedition ascent profile. The ascent was performed via the King's Trench route.



summit. The general climbing strategy was to "work high—sleep low." Specifically, at each staged camp, the team would first carry supplies to the next camp, return to lower altitude for an overnight rest, and then ascend on the following day with the remaining supplies to the next camp. A rest day was taken at Camp 2, and there were a total of 3 days when weather precluded movement at Camps 3 and 4. The West Summit (elevation 5925 m) was reached on day 14 of the expedition. The total horizontal distance from Base Camp to the West Summit was 37 km.

The ascent route did not require specialized technical climbing skills. The climbers ascended on cross-country skis, in rope teams. Each climber pulled a sled (loaded with supplies) behind him.

Two climbers (#1 and #5) were unable to continue with the expedition after the first carry of supplies to Camp 1, due to physical fatigue in both and the development of a foot skin ulceration in one (climber #1). As a result, these two climbers stayed with the Base Camp team during the rest of the expedition.

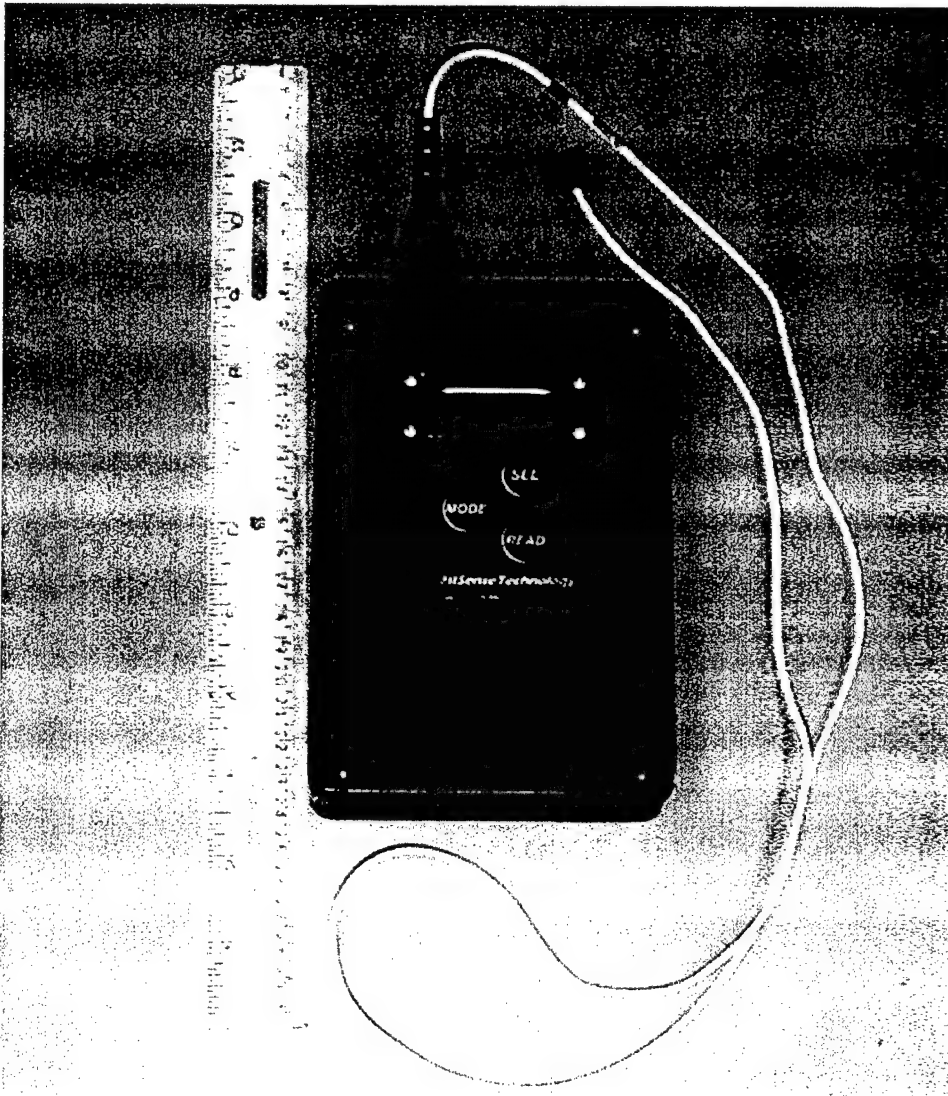
The climbing team used a Global Positioning System (GPS) receiver (Model GPS 12 XL, Garmin Inc., Olathe, KA) and kept detailed logs of their position. The altitudes recorded by the team were verified after the expedition using the logged GPS coordinates and maps of the area (8,9); the contour interval on these maps is 40 m.

CONTINUOUSLY RECORDING AMBULATORY PULSE OXIMETERS

The continuously recording ambulatory pulse oximeters were designed and built by Personal Electronic Devices, Inc. (Wellesley, MA), using an original equipment manufacturer (OEM) pulse oximetry board by Nonin, Inc. (Plymouth, MN), and a digital altimeter that measures altitude in increments of 50 feet. Each device measures 10 cm x 15 cm x 4.5 cm and weighs 381 g, including batteries (Figure 2). The device is activated and programmed by means of a serial interface to a personal computer. To maximize battery life, the device only

activates the pulse oximetry sensor at preprogrammed intervals. Because individuals at altitude will often experience nocturnal desaturations due to periodic breathing (10), the software was specifically designed to allow more frequent measurement intervals during sleep periods. During this expedition, the devices were programmed to take measurements every 15 minutes from 6:00 AM to 11:00 PM and every 15 seconds from 11:00 PM to 6:00 AM.

Figure 2. A continuously recording ambulatory pulse oximeter, equipped with a reflectance sensor.



At each programmed interval, the device takes a reading of the time, altitude, pulse, and oxygen saturation. The data are stored in nonvolatile memory, which allows the user to change batteries as needed during the course of a long expedition. At the end of the expedition, the data are downloaded through a serial connection to a personal computer. The device is capable of detecting probe disconnections and other sensing problems, and flags questionable data accordingly.

Each continuously recording ambulatory pulse oximeter allows the climber to take manual readings of the time, altitude, pulse and SpO₂. The output from each manual reading is displayed for the climber by means of a liquid crystal display (LCD) screen (Figure 2).

Each climber was given a continuously recording ambulatory pulse oximeter, two reflectance sensors (Model 8000R, Nonin Inc., Plymouth, MN), and enough 3V batteries to keep the devices functioning for at least 21 days. The climbers were initially instructed to place the sensor on their foreheads, but also told that they could place the sensor over any other bony prominence that yielded a recordable signal (as judged by the output of manual readings on the LCD screen).

At the end of the expedition, each climber was interviewed individually to gather his comments about the continuously recording ambulatory pulse oximeters. The data from each pulse oximeter were downloaded into a personal computer. Each device's clock was checked for inaccuracies against the clock of the personal computer that had been used to program the device. The ascent profiles recorded by the devices were also compared to the ascent profiles recorded by the climbing team.

RESULTS

GENERAL

None of the continuously recording ambulatory pulse oximeters performed to expectations. The problems encountered are summarized in Table 2. Four climbers stopped wearing the devices during the expedition due to human factors issues. One device returned from the expedition not responding to either manual or computer commands, and two returned in "shelf mode" (a state of the device in which no data is collected, used to maximize battery life during transport and storage). These three devices had to be sent to the manufacturer to retrieve their data. Four devices lost time during the expedition, and five of the seven devices had altimeter malfunctions.

HUMAN FACTORS ISSUES

The climbers unanimously agreed that the device is too bulky, though all thought its weight was acceptable. Some suggested that, ideally, the device should be no larger than a wristwatch. If the current size of the device cannot be reduced, the climbers recommended that a harness be developed to secure the pulse oximeter to the torso.

All stated that wearing the reflectance sensor on the forehead for protracted periods of time was very uncomfortable. As a result, four climbers refused to wear their pulse oximeters after the first carry and cache to Camp 1. Some of the climbers tried applying the sensor to other sites and found that the ulnar prominence of the wrist was a relatively comfortable site. Unfortunately, when worn on the wrist, the sensor wire was found to be too short to reach a device harnessed to the torso of tall individuals.

Changing the batteries requires that four small screws be removed from the back cover of the device. The climbers felt this was cumbersome and that the screws were too easy to lose. They suggested that a better design would be

Table 2. Summary of Problems Experienced. Problems common to all devices are discussed in the text.

Device #	Time Lost by Clock	Altimeter Problems	Other Hardware Problems	Software Problems	Human Factors Problems
1	98 hr 13 min	None		1. Entered an infinite loop during the downloading of data 2. Date counter bug (see text)	Climber stopped wearing device*
2	None	1		1. Date counter bug (see text) 2. Timer error (see text)	Climber stopped wearing device
3	256 hours	2	Unable to report SpO ₂ and time on LCD panel after first battery change	Returned in "Shelf mode"	
5	440 hr 13 min	3	Serial connector failed	1. Returned in "Shelf mode" 2. Date counter bug (see text)	Climber stopped wearing device*
6	None	2, 3		Date counter bug (see text)	
7	19 hr 39 min	None		Date counter bug (see text)	Climber stopped wearing device
8	Unknown	2	Device returned not responding to manual or computer commands	Date counter bug (see text)	

*Unable to continue climbing after the first cache and carry to Camp 1.

Key to altimeter problems:

1. Incorrect or negative values recorded, starting 6/8/99 after 19:57.
2. By report, the LCD reported the altitude to be zero after the first battery change.
3. Recorded altimetry data were highly inconsistent with GPS/map data.

one similar to the Garmin GPS, which has a spring-loaded thumbscrew that is attached to a small panel covering the battery compartment.

Each device has a serial port that is used to program it and to download data from it. Depending on the amount of data in the device, a download could take as long as 20 to 30 minutes.

HARDWARE ISSUES

All of the climbers experienced frequent disconnection of the pulse oximetry probe from the device. The probe port can accept probes with two screws, but the probe plug is not equipped with these.

Of the seven devices tested, one (serial #8) was returned to the investigator unable to respond to software commands or to manual input from the control panel. The manufacturer was, however, able to retrieve the data recorded on this device.

Four devices (serial # 1, 3, 5, 7) had clocks that ran slow during the expedition, with loss of time ranging from 19 to 440 hrs (Table 2).

Several devices suffered altimeter malfunctions. In two of these (serial #5 and #6), the recorded altitudes were inconsistent with the GPS data by several thousands of feet. In one (serial #2), the altimeter appeared to have failed intermittently, as it went through periods in which it recorded either negative values or values that were highly inconsistent with the GPS data. According to the team leader, after the first battery change, three devices (serial #3, #6 and #8) only reported altitudes of zero on the LCD screen in response to a manual query. Additionally, after 19 June 99, device #3 would only read out "ERR" for the SpO₂ and "STOP" for the time.

The serial connection on device #5 failed shortly after an initial attempt was made to download its data. The device would respond to manual keypad input but not to commands issued by the computer.

SOFTWARE ISSUES

In general, the software interface was judged by the on-site principal investigator (LS) to be easy to understand and use. A few software limitations were identified, however. First, there is no way at present to ascertain the overall status of the device at a glance; instead, each function has to be queried individually. This becomes problematic when multiple devices are being activated prior to a study, as it makes it easy to erroneously assume that an unchanged setting from a previous device is the active setting for the current device. Second, there is no command that allows the user to reset the device to its factory-set default conditions. Finally, the program opens into a small, off-center window. A more elegant interface would open the program either into a window that is centered on the screen or to a maximized window.

Three bugs were identified in the download software. First, the Excel file created by the software reported that the slow interval collection interval rate was "15 samples per minute," when in fact the device attempted to collect the slow interval samples once every 15 minutes. Second, the same file reported the fast interval collection rate to be "15 samples per minute," when in fact it collected a sample every 15 seconds (or 4 samples per minute). Finally, the download software entered an infinite loop when it attempted to download the data from one device (serial #1). Upon reaching the last data point recorded in the device, the software proceeded to attach the header information to the output and started another download cycle. This resulted in a file that contained several copies of the same download information, arranged sequentially.

In the downloaded data sets, the date counter did not turn over precisely at midnight (i.e., did not increase to the next date) after the first night. The delay in turnover increased from a few seconds to a few minutes over the course of several days.

One device (serial #2) suffered a timer error. After recording a date and time of 6/8/99 - 22:19:50, the next logged date and time was 6/8/99 - 11:42:06.

The data and timer counters continued to increment normally, but the date changeover from 6/8/99 to 6/9/99 happened at 13:27:08.

The altimeter currently reports altitudes in feet, presumably by converting barometric pressure to altitude by means of a standardized table or internal algorithm. However, the environmental variable of interest is barometric pressure, not altitude.

Two of the devices (#3 and #5) returned from the expedition in "shelf mode" (a mode used to conserve battery life during transport and storage) and would not download the data recorded during the expedition. Recovery of these data required that the devices be sent back to the manufacturer.

SAMPLE OUTPUT

An example of data collected by the continuously recording ambulatory pulse oximeter is illustrated in Figure 3. These data were collected from climber #6 on the day of ascent from Base Camp (altitude 2760 m) to Camp 1 (altitude 3460 m). Some of the desaturation phenomena that are known to occur at altitude were clearly recorded, such as an overall decrease in oxygen saturation during exertion (during the time period the team was making the climb) and the occurrence of transient episodes of desaturation during sleep.

Histograms summarizing oxygen saturations obtained from climber #6 during a succession of sleep-awake-sleep periods during the expedition are shown in Figure 4. These cover the sleep period (11 PM – 6 AM) on the night before ascent from Base Camp to Camp 1, the awake period (6 AM – 11 PM) on the day of the climb, and the sleep period (11 PM – 6 AM) after arrival at Camp 1. With increasing altitude, there was a drop in the median oxygen saturation. The median oxygen saturation was 88% (interquartile range, 87% – 89%) on the night before ascent from Base Camp to Camp 1. This declined to 86% (interquartile range, 83% - 90%) on the day of ascent, and declined further to 83% (interquartile range, 80% - 85%) on the night after arrival at Camp 1.

Figure 3. Sample 24-hour (midnight to midnight) output from a continuously recording ambulatory pulse oximeter. Oxygen saturation (SpO_2) was recorded every 15 seconds between 11 PM and 6 AM and every 15 minutes at other times. The horizontal lines represent the median SpO_2 .

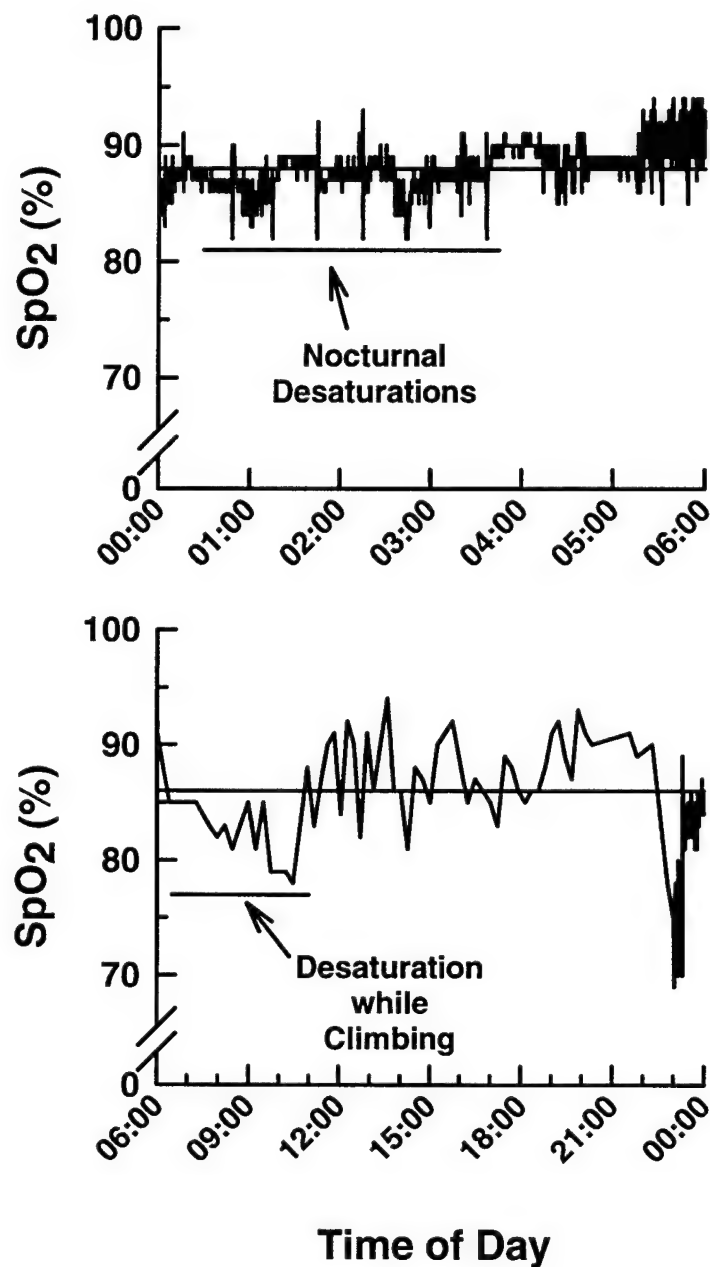
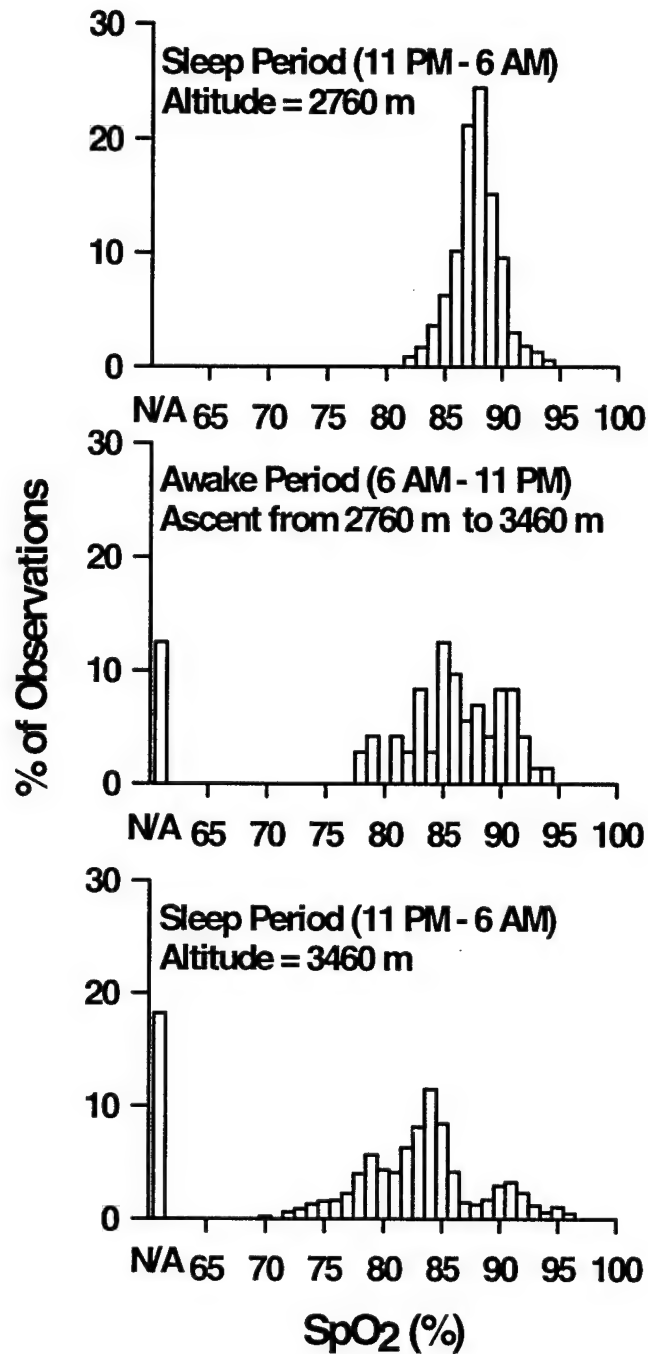


Figure 4. Distribution of oxygen saturations obtained during consecutive sleep – awake – sleep periods during the expedition. “N/A” represents data points where the device could not record data, or where a measurement was outside of the range 65%-100%.



DISCUSSION

The Hitch Hiker's Guide to the Galaxy, in a moment of reasoned lucidity which is almost unique among its current tally of five million, nine hundred and seventy five thousand, five hundred and nine pages, says of the Sirius Cybernetics Corporation products that 'it is very easy to be blinded to the essential uselessness of them by the sense of achievement you get from getting them to work at all.'

'In other words – and this is the rock solid principle on which the whole of the Corporation's Galaxy-wide success is founded – their fundamental design flaws are completely hidden by their superficial design flaws.'

Douglas Adams

So Long, and Thanks for all the Fish (1)

The continuously recording ambulatory pulse oximeters tested during the Mt. Logan expedition were bulky, uncomfortable, unreliable and difficult to use. Extensive changes in design will be required before these devices are useful as either research tools or as adjuncts to the practice of mountain medicine. We believe the following recommendations would likely improve the devices considerably:

1. The devices should be smaller. If this is not possible, each device should include a harness that will allow it to be secured to the climber without getting in the way.
2. Future devices should be thoroughly tested for obvious problems, both by the manufacturer and in altitude chamber experiments, before being tested in a field environment. Additionally, small-scale field trials are

desirable before the devices are subjected to the rigors of a high-altitude mountaineering expedition.

3. Further experiments are needed to identify and validate the optimum skin site for sensor placement. At a minimum, this site should produce reliable readings both at rest and during exercise (even in the cold), be comfortable for the user, and amenable to rotation (for example, to the contralateral side) to prevent skin irritation and breakdown. It is essential that the placement of the sensors, connectors and recording devices on the climber not hinder the physical movements required to climb safely.
4. There are significant ease-of-use issues that need to be corrected. The battery compartment should be easier to access. The sensor port needs to be redesigned to prevent accidental disconnections during use. A sensor with a longer wire will be needed if the ulnar prominence is chosen as the optimum sensor placement site.
5. The interface software should be modified (1) to allow the investigator to download data from a device even if it has entered shelf mode, (2) to make it possible for the investigator to obtain a summary of the device's settings with a single command, and (3) to reset the device to its factory-default state with a single command. The software bugs identified in this report need to be corrected, especially the date counter bug.
6. A low inspired partial pressure of oxygen is the ultimate cause of the hypoxemia that occurs at altitude. Consideration should therefore be given to having the output of the barometer/altimeter expressed as atmospheric pressure rather than as an estimated elevation.

One significant limitation of the present study is that the devices were only tested on climbers performing a glacier ascent on skis. It is possible that

climbers performing a technically challenging ascent would have identified additional human factors issues. Accordingly, plans should be made to test future devices under both non-technical and technical ascent conditions.

Despite the poor performance of this particular implementation of the concept, there are significant potential benefits to developing this technology. As shown in Figure 3, the continuously recording ambulatory pulse oximeter can record, in great detail and in real time, the oxygen saturations of a climber under the harsh conditions that prevail during a mountaineering expedition. The histograms in Figure 4 clearly illustrate the decline in median oxygen saturation that occurs with increasing altitude, but interestingly, also reveal a wider distribution of recorded oxygen saturations at the higher altitudes. During the awake period, this wider distribution is likely the result of exercise-induced desaturations that occurred during periods of physical activity (as also seen in the time course data, Figure 3). The widened and multi-modal distribution of oxygen saturations during sleep at Camp 1 may reflect the increasingly abnormal nocturnal breathing that occurs at altitude (10). Unfortunately, the histograms also reveal that 10%-20% of the data that should have been collected during two of the recording periods were missing or out of range. More reliable devices will be needed to enable investigators to explore in depth the relationship between frequency and severity of desaturation and mountain sickness under field conditions.

In addition to its potential as a research tool in mountain medicine, there are several foreseeable uses for continuously recording ambulatory pulse oximeters in pulmonary medicine. Possible uses for continuous pulse oximetry data include (a) to help determine the etiology of a patient's dyspnea, (b) to establish whether a patient with pulmonary disease would likely benefit from supplemental oxygen, and (c) to determine whether supplemental oxygen therapy is adequate to avert episodes of diurnal or nocturnal desaturation. It is noteworthy that a recent report (5) used continuous ambulatory oximetry to monitor oxygen saturation in subjects who were receiving long-term oxygen

therapy in the setting chronic obstructive pulmonary disease (COPD). It was found that, during the course of normal daily activities, unanticipated drops in oxygen saturation (to levels below the oxygen therapy target) occurred more frequently than had been anticipated based on symptoms and intermittent measurements of oxygen saturation in the outpatient clinic. These results demonstrate that intermittent measurements of oxygen saturation can miss a substantial number of clinically significant episodes of desaturation in people with chronic lung disease. A similar phenomenon may occur, in principle, in healthy subjects at altitude.

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